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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/27/2006

Tadayo Hata

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

05/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,085	Applicant(s) HATA ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/23/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The application should be reviewed for errors and conformity with domestic practice.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1, 4-9, 15 and 18 on 3/23/09 is acknowledged.

Upon reconsideration, the restriction requirement is withdrawn and the claims are rejoined.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 2/26/09 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-20 are being considered on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*,

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283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948);
Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-8 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to *Lactobacillus casei* species, the sole proper physical or physiological properties which are claim designated are that:

The species is resistant to 5% bile salts;

The species produces an antibiotic, and optionally,

Has amylolytic ability

Grows at 5° C to 45° C

Grows at pH 4.0-10.0.

All the other recited attributes are conditional or disclose an "ability".

In contrast, the specification only provides guidance for one specific strain designated as "FERM BP-10059 (FERM P-19443)". From the specification at page 24 it is clear that *Lactobacillus casei* strain of the present invention was screened by selection and acclimatization of specific *L. casei* strains. Yet the claims are directed broadly to any *L. casei* having some undefined properties.

It is also of interest to note that the resistance to bile salts of the strain *L. casei* FERM BP-10059 (FERM P-19443) is not clearly delineated in the as-filed specification. The method of

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inducing resistance is outlined, but the end-result is not shown with any particularity. Therefore, the origin of the disclosed value of 5% value is ambiguous and uncertain. In addition, no guidance is presented regarding the structure/function relationship between other *Lactobacillus casei* strains obtained from random sources having the recited properties. The disclosed species is not representative of the genus of *Lactobacillus casei* species because there is no known correlation between the resistance to 5% bile acids, which has not been demonstrated, the production of an unknown antibiotic and starch degradation, which are the only structural characteristics provided in claims 1 and 2, for example, and the functions of the claimed invention that one of skill in the art would recognize. There is no clear indication that all *Lactobacillus casei* species from random sources share common properties with the one strain obtained and which those properties might be. Thus it is not apparent that the disclosure provided is reasonably predictive of the characteristics and activity of *Lactobacillus casei* species obtained from other sources.

No guidance is presented regarding the evaluation of *Lactobacillus casei* species for the claimed properties and/or their correlation to claimed functions.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *L. casei*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

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It appears that a deposit was made in this application as filed as noted on page 8, paragraph 4 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the

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availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claims dependent thereon are confusing in the recitation of "A *Lactobacillus casei* species". This is a well known and recognized species of bacteria. From claims 3, 9 and 10 it is apparent that the claims are intended to be directed to a strain of *Lactobacillus casei*. Clarification is recommended.

Claim 1 is confusing in the recitation of conditional clauses as properties of a bacterium. The significance of the recited "properties" cannot be readily ascertained. For example, the phrases in (2) and (3) do not set forth with sufficient particularity the media, conditions and *E. coli* strain(s) involved in "when a growth-promoting culture medium is inoculated with the species and *Escherichia coli* in the same count and subjected to anaerobic mixed culturing at 37°C, the final count of lactobacilli is 50% or more of the coliform count" or (3) "Upon cultivation in an appropriate culture medium, the final pH value is 4.0 or below, and the highest acidity is 1.5% or more", and cannot be deemed to constitute a meaningful "property" of "a *Lactobacillus casei* species".

In claim 2, it is uncertain what constitutes "widely-used antibiotics" in this context.

At least claims 4-6 and 11-14 are confusing in the recitation of "as a primary active ingredient". The concentration intended cannot be readily assessed. This is compounded by the addition of an antibiotic, without an indication of the concentration thereof. It is at least

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ambiguous whether the antibiotic, for example, is or is not "a primary active ingredient" in this context.

Claims 7-9 and 15-20 are vague, indefinite, improper and confusing in the recitation of the process step "is applied..." in a composition claim. Processes and compositions belong in different statutory classes of invention. In this regard, the claims are further vague indefinite and confusing in that it is at least ambiguous whether the composition as claimed does or does not contain a bactericidal disinfectant as an ingredient. For purposes of examination, it is apparent that it does not include the a disinfectant, since claim 8 is directed to the ingredients "as principal components" which is distinct from "as a primary active ingredient". In addition, in claim 8 the "as principal components" recited cannot be readily assessed in this context.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hata *et al.* (U.S. Patent No. 4,314,995)

The claims appear to be drawn to a *Lactobacillus casei* species which produces an antibiotic and which is resistant to bile acid and which may have certain functional properties.

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The cited reference discloses a *Lactobacillus casei* strain which appears to be identical to the presently claimed strain (see, e.g., Table 1 and Table 7) since it similarly is resistant to bile and produces an antibiotic. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is disclosed as being of the same class as that of the microorganism claimed, is taught to have similar physiological properties, such as resistance to bile, and is similarly useful as a therapeutic agent against infections in humans due to its antibiotic properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

As noted in the rejection under 35 U.S.C § 112, the various intended uses, particularly with respect to "prevention" and the method steps in the composition claims are not directed to particular properties of *L. casei*, and cannot be considered as claim limitations; for example, with respect to the "is applied" clause at least in claims 7-8 and 15-20 the application to affected areas is not informative regarding the composition claimed. Moreover, the actual concentration of *L. casei* in claims 4-20 is not clearly delineated, particularly when applied with a bactericidal agent or an antibiotic.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asahara *et al.* (Antimicrobial Agents and Chemotherapy, June 2001, Vol. 45, p. 1751-1760) in light of Ouwehand *et al.* (Journal of Food Science, Vol. 66, No. 6, pages 856-858, 2001.)

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The claims are drawn to a *Lactobacillus casei* species which produces an antibiotic and which is resistant to bile acid and which may have certain functional properties.

The cited reference discloses a *Lactobacillus casei* strain, the Shirota strain, which appears to be identical to the presently claimed strain since it similarly is resistant to bile and produces an antibiotic. See, e.g., Asahara *et al.* page 1753, paragraph 2, et seq. and Ouwehand *et al.*, page 856, last 2 lines. That the strain is resistant to 10% bile is evidenced by its viability in the mucus adhesion test. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is disclosed as being of the same class as that of the microorganism claimed, is taught to have similar physiological properties, such as resistance to bile, and is similarly useful as a therapeutic agent against infections in humans due to its antibiotic properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

As noted in the rejection under 35 U.S.C § 112, the various intended uses, particularly with respect to "prevention" and the method steps in the composition claims are not directed to particular properties of *L. casei*, and cannot be considered as claim limitations; for example, with respect to the "is applied" clause at least in claims 7-8 and 15-20 the application to affected areas is not informative regarding the composition claimed. Moreover, the actual concentration of *L. casei* in claims 4-20 is not clearly delineated, particularly when applied with a bactericidal agent or an antibiotic.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims directed to the specific strain *Lactobacillus casei* FERM BP-10059 would be allowable upon resolution of all 35 U.S.C § 101 and 35 U.S.C § 112 issues. There would have

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been no motivation for one of ordinary skill in the art to select a strain of *Lactobacillus casei* having the properties as disclosed for *Lactobacillus casei* FERM BP-10059 at Table 1, Specification page 25 at the time the claimed invention was made..

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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